

Claims

1. A stable pharmaceutical composition of granulocyte-colony stimulating factor (G-CSF), wherein the composition has a pH value of above 4.0 and comprises:
 - a therapeutically effective amount of G-CSF, and
 - an acid and is free of surfactants.
2. The composition of claim 1, wherein pH value of the composition is in the range from 4.2 to 4.8.
3. The composition of claim 2, wherein pH of the composition is at about 4.4.
4. The composition according to any one of preceding claims, optionally further comprising:
 - a polyol and/or
 - a pH buffering system and/or
 - one or more pharmaceutically acceptable excipient(s).
5. The composition according to any one of preceding claims, wherein G-CSF is non-glycosylated.
6. The composition according to any one of preceding claims, wherein the composition is aqueous.
7. The composition of claim 1, wherein the acid is selected from the group comprising acetic acid, HCl, maleic acid, glutamic acid, methansulphonic acid and citric acid.
8. The composition of claim 7, wherein the acid is selected from the group comprising acetic acid and HCl.
9. The composition of claim 4, wherein the polyol is selected from the group comprising sorbitol, glycerol, inositol and mannitol.
10. The composition of claim 9, wherein the selected polyol is sorbitol.
11. The composition of claim 10, wherein sorbitol is comprised in the range from about 1% to about 10%.
12. The composition of claim 10, wherein sorbitol is comprised in the range from about 3% to about 8%.

13. The composition of any one of claims 1 to 11, wherein the pH buffering system is selected from the group comprising acetic acid/acetate and phosphoric acid/phosphate.
14. The composition of claim 13, wherein the selected pH buffering system is acetic acid/acetate.
15. The composition of claim 14, wherein the concentration of acetic acid is comprised in the range from about 0.15 mM to about 15 mM.
16. The composition of claim 15 wherein the concentration of acetic acid is comprised in a range from about 1.5 mM to about 10 mM.
17. A process for preparing a composition containing G-CSF wherein the composition of any of claims of 1 to 16 is prepared.
18. Use of a composition of any one of claims 1 to 17 for the preparation of a medicament for the treatment and/or prevention of diseases indicated for G-CSF.
19. Use of a composition of any one of claims 1 to 17 for treatment and/or prevention of diseases indicated for G-CSF.